of the instrument. The remaining four copies of the form may be copies of the original. Attachments should be fully identified and referenced to the question(s) on the form to which they relate.

(e) A single application (in the requisite number of copies) may be submitted for any quantity of the same type or model of foreign instrument provided that the entire quantity is intended to be used for the same purposes and provided that all units are included on a single purchase order. A separate application shall be submitted for each different type or model or variation in the type or model of instrument for which duty-free entry is sought even if covered by a single purchase order. Orders calling for multiple deliveries of the same type or model of instrument over a substantial period of time may, at the discretion of the Director, require multiple applications.

(f) Failure to answer completely all questions on the form in accordance with the instructions on the form or to supply the requisite number of copies of the form and supporting documents may result in delays in processing of the application while the deficiencies are remedied, return of the application without processing, or denial of the application without prejudice to resubmission. Any questions on these regulations or the application form should be addressed to the Director.

[47 FR 32517, July 28, 1982, as amended at 50 FR 11501, Mar. 22, 1985]

§ 301.4 Processing of applications by the Department of the Treasury (U.S. Customs Service).

(a) *Review and determination.* The Commissioner shall date each application when received by Customs. If the application appears to be complete, the Commissioner shall determine:

(1) Whether the institution is a nonprofit private or public institution established for research and educational purposes and therefore authorized to import instruments into the U.S. under tariff item 851.60. In making this determination the Commissioner will generally review the application to determine if the applicant has attached a copy of the letter from the Internal Revenue Service (IRS) granting the institution nonprofit status (exemption from Federal income tax) under section 501(c)(3) of the IRS Code or will determine if the institution is listed in a current edition of ''Cumulative List of Exempt Organizations'';

(2) Whether the instrument falls within the classes of instruments eligible for duty-free entry consideration under tariff item 851.60 (For eligible classes see Headnote 6(a), part 4, Schedule 8, TSUS); and

(3) Whether the instrument which is the subject of the application is intended for the exclusive use of the applicant institution and is not intended to be used for commercial purposes. For the purposes of this section, commercial uses would include, but not necessarily be limited to: Distribution or sale of the instrument by the applicant institution; any use by, or for the primary benefit of, a commercial entity; or use of the instrument for demonstration purposes in return for a fee or other valuable consideration. In making the above determination, the Commissioner may consider, among other things, whether the results of any research to be performed with the instrument will be fully and timely made available to the public. For the purposes of this section, use of an instrument for the treatment of patients is considered noncommercial.

If any of the Commissioner's determinations is in the negative, the application shall be found to be outside the scope of the Act and shall be returned to the applicant with a statement of the reason(s) for such findings.

(b) *Forwarding of applications to the Department of Commerce.* If the Commissioner finds the application to be within the scope of the Act and these regulations, the Commissioner shall (1) assign a number to the application and (2) forward one copy to the Secretary of the Department of Health and Human Services (HHS), and two copies, including the one that has been signed in the original, to the Director. The Commissioner shall retain one copy and return the remaining copy to the applicant stamped ''Accepted for Transmittal to the Department of Commerce.'' The applicant shall file the stamped copy of the form with the Port when formal entry of the article is made. If entry has already occurred

under a claim of tariff item 851.60, the applicant (directly or through his/her agent) shall at the earliest possible date supply the stamped copy to the Port. Further instructions for entering instruments are contained in § 301.8 of the regulations.

[47 FR 32517, July 28, 1982; 47 FR 34368, Aug. 9, 1982, as amended at 50 FR 11501, Mar. 22, 1985]

§ 301.5 Processing of applications by the Department of Commerce.

(a) *Public notice and opportunity to present views.* (1) Within 10 days of receipt of an application from the Commissioner, the Director shall make a copy available for public inspection during ordinary business hours of the Department of Commerce. Unless the Director determines that an application has deficiencies which preclude consideration on its merits (e.g., insufficient description of intended purposes to rule on the scientific equivalency of the foreign instrument and potential domestic equivalents), he shall publish in the FEDERAL REGISTER a notice of the receipt of the application to afford all interested persons a reasonable opportunity to present their views with respect to the question ''whether an instrument or apparatus of equivalent scientific value for the purpose for which the article is intended to be used is being manufactured in the United States.'' The notice will include the application number, the name and address of the applicant, a description of the instrument(s) for which duty-free entry is requested, the name of the foreign manufacturer and a brief summary of the applicant's intended purposes extracted from the applicant's answer to question 7 of the application. In addition, the notice shall specify the date the application was accepted by the Commissioner for transmittal to the Department of Commerce.

(2) If the Director determines that an application is incomplete or is otherwise deficient, he may request the applicant to supplement the application, as appropriate, prior to publishing the notice of application in the FEDERAL REGISTER. Supplemental information/material requested under this provision shall be supplied to the Director in two copies within 20 days of the date of the request and shall be subject to the certification contained in Question 11 of the form. Failure to provide the requested information on time shall result in a denial of the application without prejudice to resubmission.

(3) *Requirement for presentation of views (comments) by interested persons.* Any interested person or government agency may make written comments to the Director with respect to the question whether an instrument of equivalent scientific value, for the purposes for which the foreign instrument is intended to be used, is being manufactured in the United States. Except for comments specified in paragraph (a)(4) of this section, comments should be in the form of supplementary answers to the applicable questions on the application form. Comments must be postmarked no later than 20 days from the date on which the notice of application is published in the FEDERAL REGISTER. In order to be considered, comments and related attachments must be submitted to the Director in duplicate; shall state the name, affiliation and address of the person submitting the comment; and shall specify the application to which the comment applies. In order to preserve the right to appeal the Director's decision on a particular application pursuant to § 301.6 of these regulations, a domestic manufacturer or other interested person must make timely comments on the application. Separate comments should be supplied on each application in which a person has an interest. However, brochures, pamphlets, printed specifications and the like, included with previous comments, if properly identified, may be incorporated by reference in subsequent comments. If the Director knows of the availability of a domestic instrument which may be comparable to the foreign instrument, he may: (i) Require the applicant to compare the domestic instrument with the foreign instrument; or (ii) compare the two instruments whether or not comments are received from a domestic manufacturer on the specific application.

(4) *Comments by domestic manufacturers.* Comments of domestic manufacturers opposing the granting of an application should: